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ANNEX 1

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to the

COMMISSION IMPLEMENTING REGULATION (EU) …/...

approving pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated as an existing active substance for use in biocidal products of product-type 18

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Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance[1]	Reference structural characteristics[2]	Date of approval	Expiry date of approval	Product type	Specific conditions
Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated	IUPAC Name: Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica EC No: 272-697-1 CAS No: 68909-20-6	998 g/kg (purity of core measured after ignition).	- Carbon content: 3.0-4.0%; - Primary particle size: 6.9-8.6 nm; - Specific surface area: 217-225 m^2/g; - Size of stable aggregated particles: > 70 nm; - Surface treatment : with > 90% of the surface surface-treated with hexamethylsilazane (CAS 999-97-3)	1 November 2018	31 October 2028	18	The authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. 2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users. 3) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[3] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[4] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated in accordance with Article 89(1) of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

[2] The structural characteristics indicated in this column were the ones of the active substance used for the evaluation made in accordance with Article 89(1) of Regulation (EU) No 528/2012.

[3] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).